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RE: Response to Restriction Requirement

SERIAL NO.: 10/535,002

DOCKET NO.: X-16114

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**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants	:	Mader, et al.	)
			)
Serial No.	:	10/535,002	)
			) Group Art Unit:
Filed:		May 12, 2005	) 1626
			)
For	:	Antitumor Compounds and Methods	) Examiner:
			) S. Young
			)
Docket No.	:	X-16114	)

**Response to Restriction Requirement**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants hereby submit the following arguments in connection with a restriction requirement dated May 16, 2006 in the above referenced patent application.

The Examiner submitted the following six-way restriction requirement under 35 U.S.C. 121 and 372 on the present patent application:

Group I where A is phenyl, cyclopentadienyl, cyclobutyl, or cyclopentyl;

Group II where A is benzofuryl;

Group III where Ar is benzothien-2-yl, benzothien-5-yl, or benzothien-6-yl;

Group IV where Ar is thieno[3,2-b]pyridine-2-yl;

Group V where Ar is 1-(C<sub>1-6</sub> alkyl)indol-2-yl; and

Group VI which is a method of use claim, Claim 4.

As noted by the Examiner, these groups are not all inclusive of Applicant's claimed subject matter.

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The Examiner has asserted that the present application contains multiple inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The Examiner has also asserted that due to the different classes found among the compounds of the formula (I), e.g. heterocyclic and carbocyclic ring systems, a precise listing of inventive groups cannot be made. Applicants respectfully traverse this restriction.

The present application is an international application which has entered the U.S. national stage under 35 U.S.C. §351. Restriction is therefore governed by unity of invention. MPEP 1893.03(d). Applicants urge that there is a technical relationship among the claimed inventions involving a special technical feature and thus, unity of invention does exist.

According to the unity of invention standard set forth in PCT Rule 13.2, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding "special technical features" The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.

Under (d) of PCT Gazette-Section IV, Annex B, Part 1, a copy of which is attached to this response for the Examiner's convenience, there are three particular situations for which the method for determining unity of invention contained in Rule 13.2 is explained in greater detail. One of those situations is Markush practice.

The situation involving Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2 shall be considered to be met when the alternatives are of a similar nature.

(i) When Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and  
(emphasis added)

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(B)(1) A common structure is present, i.e. a significant structural element is shared by all of the alternatives; or (emphasis added)

(B)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

(ii) In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art. The structural element may be a single component or a combination of individual components linked together.

(iii) In paragraph (f)(i)(B)(2), above, the words "recognized class of chemical compounds mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted for the other, with the expectation that the same intended result would be achieved.

(iv) The fact that the alternatives of a Markush grouping can be differently classified shall not, alone, be considered to be justification for a finding of a lack of unity of invention. PCT Gazette-Section IV, Annex B, Part 1 (f)

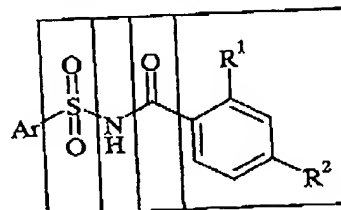
Applicants urge that a special technical feature exists for the formula as provided in the present application. This Markush grouping possesses a similar nature because the alternatives for compounds of the formula provided all have the common property of being useful as antitumor agents. Furthermore, the alternatives of chemical compounds are of a similar nature since a common core structure occupying a large portion of all of the structures – a 2,4-disubstituted benzoyl sulfonamide is present for the claimed invention.

Applicants ask the Examiner to note that as per paragraph (ii), "a structurally distinctive portion in view of existing prior art" only relates to the "or in case the

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compounds have in common only a small portion of their structures" (emphasis added). This is not the case here, where the common core consists of not only a 2,4 disubstituted

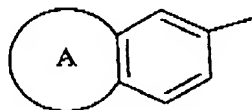


phenyl but also a three-part linker of  $-\text{SO}_2-$ ,  $\text{NH}$ , and  $\text{C}(\text{O})$ .

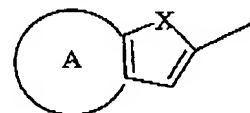
Further, the Examiner has asserted that due to the different classes found among the compounds of the formula I, e.g., heterocyclic and carbocyclic ring systems, a precise listing of inventive groupings cannot be made. As per paragraph (iv) of Annex B, the fact that the alternatives of a Markush grouping can be differently classified shall not, alone, be considered to be justification for a finding of a lack of unity of invention.

Though the alternatives of the Markush grouping can be differently classified, they are easily searchable. Variable Ar consists of specific bicyclic and tricyclic aryl and heteroaryl moieties. All of the Ar substituents attach to the 2,4-disubstituted benzoyl

sulfonamide core through either a phenyl,



, or a five-membered



heteroaromatic ring in which the heteroatom is in a fixed position, making these easily and conveniently searchable.

Additionally, the method claim, Claim 4, cannot be restricted from the compounds. Applicants direct the Examiner's attention to PCT Gazette-Section IV, Annex B, Part 2, Section I, page 52. This section of the cited reference provides examples concerning unity of invention under Rule 13.1/13.2. Applicants note specifically Example 1 where it clearly states that unity of invention exists between a claim to a method of manufacturing chemical "substance X", a claim to "substance X" and a claim to the use of "substance X" because these claims possess a common special

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technical feature, i.e., "substance X". This is the same scenario presented by Applicants' claims 1 and 5.

In the present case, Applicants have claimed compounds with a 2,4-disubstituted benzoyl sulfonamide core (the substance) and a method of using compounds with a 2,4-disubstituted benzoyl sulfonamide core (the use of the substance). Accordingly, the special technical feature common to these claims is a 2,4-disubstituted benzoyl sulfonamide core, and as such, under Rule 13.2, there is unity of invention and the claims must be examined together.

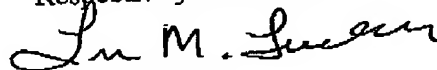
In view of these points, the pending claims, Claims 1-5, meet the criteria of unity of invention under Rules 13.1/13.2. Applicants request that the restriction requirement be removed from the present application.

In the event that the Examiner does not withdraw the restriction requirement, and in order to be responsive, Applicants elect Group III with traverse.

Please charge any fees or credit any overpayment in connection with this application which may be required by this or any related paper to Deposit Account No. 05-0840.

If the Examiner has any questions, or would like to discuss any matters in connection with this application, she is invited to contact the undersigned at (317) 277-3537.

Respectfully submitted,



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16 June 2006  
Attachment: PCT ANNEX B-Section IV, August 30, 2001